

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

In re: BAIR HUGGER FORCED AIR  
WARMING DEVICES PRODUCTS  
LIABILITY LITIGATION

MDL No. 15-2666 (JNE/FLN)

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This Document Relates To:  
*All Cases*

**PLAINTIFFS' MEMORANDUM IN  
SUPPORT OF MOTION TO EXCLUDE  
TESTIMONY OF JONATHAN M.  
BORAK UNDER FED. R. EVID. 702**

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**I. INTRODUCTION**

*Daubert's* gatekeeping requirement ensures that expert testimony—regardless of which party is offering it—is based on a factually reliable foundation, not conjecture or second-hand opinion. Without court intervention, unreliable opinion testimony has strong potential to mislead and confuse the jury. Dr. Borak's testimony poses this very threat.

Dr. Borak claims the McGovern study has no validity whatsoever. As a litigation expert, Dr. Borak was obligated to base his opinions on objectively verifiable sources of information such as published scientific articles showing that he has followed a recognized scientific method. But Dr. Borak did not independently review the findings of the McGovern study. He just relied on Dr. Holford's statistical manipulations of an incomplete and draft data set of the McGovern study, assuming they were based on valid assumptions, and uncritically adopted them as his own conclusions. Dr. Borak does so at his own peril.

Since Dr. Borak merely adopted Dr. Holford's conclusions on issues critical to his own opinion, the underlying flaws of Dr. Holford's approach rise to the fore. Dr. Holford's methodology—to the extent he followed one—is rife with false assumptions, speculation,

and double-standards, and he compounded these errors by building his calculations on one misstep after another. Dr. Holford did not submit his unique data reanalysis for peer review or publication, and Dr. Borak made no effort to validate it. In effect, Dr. Borak repeats Dr. Holford's errors by accepting them as fact. Dr. Borak also ignored numerous contrary published studies and took others out of context, casting further doubt on the reliability of his testimony. Some of Dr. Borak's opinions, including his cursory contention that the Hawthorne Effect confounded the results of the McGovern study, have no factual support.

In short, Dr. Borak's opinions rest on a quagmire of false assumptions, speculation, and obfuscation—the precise type of testimony that *Daubert* and Rule 702 prohibit. The Court should exclude his so-called “expert” testimony for all the reasons set forth below.

## **II. BACKGROUND**

On June 2, 2017, Defendants disclosed the report of their retained expert, Jonathan Borak, to attack the opinions of Plaintiff's general causation expert, epidemiologist and public health specialist, Dr. Jonathan Samet. Ex.A, Borak Rpt. Although Dr. Borak is a part-time clinical professor of epidemiology and public health, *id.* at 1, he spends the vast majority of his time running his consulting company advising lawyers and industry. Ex.B, Borak Dep. at 39:14-41:11. He is not a board-certified epidemiologist, nor does he have a degree in epidemiology. *Id.* at 17:23-18:10. He has no expertise in infectious medicine, anesthesiology, normothermia, hypothermia, or orthopedic surgery. *Id.* at 19:10–24. Nor is he a statistician. *Id.* at 19:25-20:2. Dr. Borak ultimately concedes that he lacks expertise to opine on the mechanisms by which the Bair Hugger Forced Air Warming Blanket (“BairHugger”) can cause deep joint infection (“DJI”). *Id.* at 81:4–10; 83:9–14; 92:13–23.

Dr. Borak opines repeatedly that the peer-reviewed and published McGovern epidemiological study<sup>1</sup> is “flawed” and lacks validity, and therefore provides no evidence to support an association between BairHugger use and DJI. Ex.A, Borak Rpt. at ¶¶ 54–59, 67, 71. For his conclusion that the McGovern study contains statistical errors, Dr. Borak relies entirely on Dr. Holford’s report and analysis—a post-hoc manipulation of an incomplete data set that does not match the data in Figure 7 of the McGovern study. Ex.A, Borak Rpt. at ¶¶ 49–53. Dr. Borak made no independent effort to determine whether the data set Dr. Holford used for his statistical manipulation is correct; he just assumes so. Ex.B, Borak Dep. at 39:4–10. Dr. Borak thus concedes—as he must—that if Dr. Holford’s recalculations of the McGovern data are wrong, then he is also wrong. *Id.* at 223:15–21.

Dr. Borak’s other opinions on confounders and hospital infection rates parrot those of Dr. Holford. Ex.A, Borak Rpt. at ¶¶ 27–46. Following Dr. Holford, he selectively lifts statements out of context, while ignoring contrary published studies and the testimony of the McGovern study authors. Also like Dr. Holford, he refused to consider non-epidemiological sources of causation evidence—a generally accepted and important factor for drawing causal inference. Ex.B, Borak Dep. at 78:2-79:5; 81:4–10; 83:9–14; 92:13–23.

### III. LEGAL STANDARDS

Federal Rule of Evidence 702 permits expert witnesses to testify if the subject of their testimony is relevant, the witnesses are qualified to express their opinions, and the evidence upon which they base their testimony is reliable. *Polski v. Quigley Corp.*, 538

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<sup>1</sup> Ex.C, P.D. McGovern, *An Investigation of Theatre Ventilation, Patient Warming and Joint Replacement Infection in Orthopaedics*, 93B:11 J BONE & JOINT SURG 1537 (2011).

F.3d 836, 839 (8th Cir. 2008). Courts are gatekeepers of expert evidence “to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999).

Expert testimony must be trustworthy to be reliable. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 590 (1993). That is, the testimony must be appropriately validated. *Id.* Four nonexclusive factors control the reliability of expert testimony: (1) whether the theory or technique can be and has been tested; (2) whether the technique has been subject to peer review and publication; (3) the technique’s known or potential rate of error; and (4) the theory or technique’s acceptance within the relevant field. *Id.* at 593–94.

The Eighth Circuit considers additional factors as well: “whether the expertise was developed for litigation or naturally flowed from the expert’s research; whether the proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case.” *Polski*, 538 F.3d at 839. The party seeking admission of expert testimony has the burden of demonstrating its reliability. *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1042 (D. Minn. 2007).

A “very significant” criterion of reliability is whether the expert’s testimony is based on research independent of litigation. *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (*Daubert II*). If the proffered expert testimony is not based on independent research, the party proffering it must offer other objective, verifiable evidence and explain precisely how the expert testimony is based on objective sources—a learned treatise, the policy statement of a professional association, a published article in a reputable

scientific journal, or the like—to show that the expert followed the scientific method as practiced by (at least) a recognized minority of scientists in the field. *See id.* at 1317–19.

Where the factual basis, data, or the methodology employed by the expert witness are sufficiently called into question, the court must determine not only if the testimony is reliable, but also whether the testimony has a valid connection to the pertinent inquiry. *See Kumho Tire Co.*, 526 U.S. 137 at 149. Expert testimony must therefore “logically advance[] a material aspect of the proposing party’s case.” *See, e.g., Daubert II*, 43 F.3d at 1315.

The court should not admit opinion evidence “that is connected to existing data only by the *ipse dixit* of the expert.” *General Elec. Co. v. Joiner*, 522 U.S. 136, 137 (1997). Nor should it admit opinion evidence that hinges on an expert’s unique methodology. *Groobert v. President and Dir. of Georgetown Coll.*, 219 F. Supp. 2d 1, 9 (D.D.C. 2002). Moreover, an expert’s primary reliance on the opinions of other experts for litigation purposes “raises serious reliability questions,” especially if the expert has not tested the other expert’s underlying data to ensure its accuracy. *E.g., In re ConAgra Foods, Inc.*, 302 F.R.D. 537, 556 (C.D. Cal. 2014). Under these circumstances, a court may conclude “there is simply too great an analytical gap between the data and the opinion.” *Joiner*, 522 U.S. at 146.

#### **IV. ARGUMENT**

The *McGovern* article is a published, peer-reviewed epidemiological study that directly investigated the association between DJI and BairHugger. It reported a statistically significant 3.8 fold increased risk of DJI with BairHugger use compared to a conductive warming blanket. As is routinely done in peer-reviewed literature, the authors described their methods, analysis, and findings. The *McGovern* paper grew out of pre-litigation

research, passed peer review, and was published in a respected medical journal; it has never been retracted. Nor has 3M, Dr. Borak, or any other expert called for its retraction. There are no epidemiological studies that contradict or disprove the association between BairHugger and DJI. Publication in a reputable peer reviewed journal is a significant indication that research meets “at least the minimal criteria of good science.” *Daubert II*, 43 F.3d at 1318; *accord Luzon v. Senco Prods., Inc.*, 270 F.3d 681, 693 (8th Cir. 2001).

Dr. Borak suggests that the McGovern study provides *no* evidence of an association because of the study’s supposed “flaws.” This opinion is not only contrary to legal and scientific standards, but it has great potential to mislead jurors. Published and peer-reviewed epidemiological studies are well-taken in mass tort suits. *See In re Viagra Prods. Liab. Litig.*, 572 F. Supp. 2d. 1071, 1081 (D. Minn. 2008); *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 289 F. Supp. 2d 1230, 1239 (W.D. Wa. 2003). And the “flaws” that Dr. Borak claims invalidate the McGovern study only take shape as a result of Dr. Holford’s unorthodox and unreliable remix of an incomplete data set. Dr. Borak thus admits that if the McGovern study “holds up,” he is wrong. Ex.B, Borak Dep. at 211:5–22.

Dr. Borak’s opinion that the McGovern study provides no evidence of causation requires strict scrutiny given that it is litigation driven and relies in large part on Dr. Holford’s unreliable arguments and data manipulations, which have never been peer-reviewed or published. As explained below, Defendants have failed to meet their burden of demonstrating that Dr. Borak’s testimony is reliable and admissible under Rule 702.

**A. Dr. Borak's Opinions Regarding So-Called "Data Irregularities" in the McGovern Study Are Not Only Unreliable But Ultimately Inadmissible**

Dr. Borak maintains that an "apparent" data tabulation error "importantly impacted the interpretation" of the McGovern study results, making it invalid. Ex.A, Borak Rpt. at ¶¶ 49-53. Though he cites Albrecht Exhibit 10, McGovern Exhibit 16, and selected snippets of deposition testimony as evidence for his opinion, Dr. Borak did not independently review any of those documents in detail or conduct his own statistical analysis of the data; instead, he blindly accepts Dr. Holford's attempt to mix and match data as the factual basis for his conclusion. Ex.B, Borak Dep. at 38:15-39:10; 152:13-22. This alone is grounds for excluding Dr. Borak's opinion. *See, e.g., In re ConAgra Foods, Inc.*, 302 F.R.D. at 556.

As described in Plaintiffs' memorandum to exclude Dr. Holford's testimony, Dr. Holford's mistabulation theory depends entirely on an incomplete data set that contradicts Figure 7 of the McGovern study and which none of the McGovern authors could verify as the data they used to write the study. *See* Pls.' Mem. to Exclude Holford at 8-12. Because Dr. Holford's testimony on this point rests on a baseless foundation, so too does Dr. Borak's. After all, Dr. Borak does not know one way or another whether a tabulation error exists in the study; he simply assumes Dr. Holford's analysis is true. *See* Ex.A, Borak Rpt. at ¶ 49 ("apparent" error). The failure to reason from known facts to reach a conclusion "turns scientific analysis on its head." *Sorensen By and Through Dunbar v. Shaklee Corp.*, 31 F.3d 638, 649 (8th Cir. 1994). Likewise, expert opinions based on factually unsupported assumptions are subject to exclusion under Rule 702. *Id.* at 649. Dr. Borak's opinion on the alleged data irregularities of the McGovern study is unreliable and should be excluded.

**B. Dr. Borak's Theory of Confounding Runs Afoul of the Generally Accepted Scientific Methodology for Identifying Confounding Variables**

Borrowing mainly from Dr. Holford's report, Dr. Borak launches several scattershot attacks on the McGovern study for failing to control for hypothetical confounders, including antibiotics, MSSA screening, skin preparation, and thromboprophylaxis protocols. Ex.A, Borak Rpt. at ¶¶ 32–46. This “spaghetti approach” is not relevant or helpful to the Court or jury in understanding the question of general causation. *See, e.g., Indep. Towers of Washington v. Washington*, 350 F.3d 925, 929 (9th Cir. 2003) (discounting evidence in plaintiff's brief for taking the “spaghetti approach” because it “heaved the entire contents of a pot against the wall in hopes that something would stick”). More fundamentally, however, Dr. Borak's testimony is unreliable because he disavows the generally accepted methodology epidemiologists use to identify confounding variables.

Dr. Borak agrees that a confounder, by definition, must be *associated* with the outcome of interest before it can be identified as one. Ex.A, Borak Rpt. at ¶ 18 (citing REFERENCE MANUAL at 591). In the face of this well-accepted methodology, Dr. Borak identifies variables that allegedly confounded the findings of the McGovern study without first investigating whether those variables are in fact associated with higher DJI rates. The Eighth Circuit has denounced such backwards reasoning. *See Sorenson*, 31 F.3d at 649.

Specifically, Dr. Borak opines that “if” any of the factors he identifies is associated with DJI, “then” it would be a confounder. *See* Ex.A, Borak Rpt. at ¶ 32 (“If use of gentamicin alone was less effective against SSI, then that could have caused GH to be associated with higher infection rates.”); *id.* at ¶ 38 (“To the extent that [MSSA screening]

reduced SSI, it would have been almost entirely during the non-FAW period.”); *see also id.* at ¶ 35 (“in that case”); *id.* at ¶ 40 (“to the extent”); *id.* at ¶ 48 (“in that case”). Dr. Borak had no factual basis to identify the factors he comes up with as confounders, nor does he cite a single study to support his hypothetical yet unsubstantiated associations. If anything, the scientific literature contradicts his *a priori* assumption, finding no significant association between the variables he cites and the outcome of interest—DJI. Dr. Borak failed to consider this contrary evidence in developing his opinions, which further shows that he did not follow a reliable methodology when identifying confounding variables.

### **1. Changes in SSI Protocols Did Not Confound the McGovern Study.**

In his report, Dr. Borak repeats arguments made by Dr. Holford that DJI rates at Wansbeck Hospital were “out of control” and that changes in protocols to reduce surgical site infections (“SSI”) during the McGovern study period accounted for the difference in DJI rates between the BairHugger and conductive blankets. Ex.A, Borak Rpt. at ¶¶ 27–28.

Dr. Borak misleadingly states that Dr. Reed acknowledged that Wansbeck was a “high outlier” for SSI rates. Ex.A, Borak Rpt. at ¶ 27. In fact, Dr. Reed explained that not every hospital in the U.K. reports as much infection data as Wansbeck as part of routine surveys; infection rates reported in survey data are therefore known to be low. Government advisors on infection rates in the U.K., moreover, acknowledge that reported infection rates are unrealistically low due to “poor surveillance systems.” Ex.D, Reed Dep. at 67:9–15.

Dr. Borak also ignored 3M’s own analysis of national infection rates during the McGovern study period, prepared by Mr. Albert Van Duren. Ex.E, Van Duren Dep. Exhibit 77 (3MBH0554267); Ex.F, Van Duren Dep. at 275:1-276:25. During the study period, DJI

rates in the United States were approximately 4.5%. *Id.* To be sure, this figure is significantly higher than the 2.91% DJI rate at Wansbeck, not lower, as Dr. Borak asserts.

Failing to cite any evidence, Dr. Borak relies on Dr. Holford's assumption that other infection controls implemented at Wansbeck Hospital as part of an SSI bundle confounded the McGovern study. Ex.A, Borak Rpt. at ¶ 28. As Dr. McGovern testified, the scientific literature does not show that these changes significantly affect DJI rates. Ex.G, McGovern Dep. at 408:17-409:14. For example, Wansbeck switched from standard wound dressings to the "Jubilee" dressing, but the only study on point found that DJI rates were not significantly different among patients who used either dressing. Ex.H, McGovern Ex. 22.

If that were not enough to exclude his opinion on SSI interventions, Dr. Holford admitted that he did not independently analyze the impact of SSI bundles on DJI, Ex.I, Holford Dep. at 367:15-368:2, while he further acknowledged that surgical site infections (SSI) is "not the same thing" as deep joint infections. *Id.* at 304:13-306:10. Dr. Borak simply relied on Dr. Holford's apocryphal analysis and thus copied his mistake. He did not even distinguish the two different types of infection (SSI and DJI) anywhere in his report. Ex.B, Borak Dep. at 83:15-84:4. In sum, Dr. Borak's opinion regarding the alleged impact of SSI measures on DJI has no support in the published literature, and it improperly depends on Dr. Holford's unsupported assumptions. Because Dr. Borak's second-hand testimony on SSI is just as unreliable as Dr. Holford's testimony, it should be excluded.<sup>2</sup>

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<sup>2</sup> As part of his SSI bundle argument, Dr. Borak also adopted Dr. Holford's time trend analysis, alleging that the McGovern authors "cherry-picked" data by not using an earlier start date for the study. Ex.A, Borak Rpt. at ¶ 29. Again, Dr. Borak relies on Dr. Holford's baseless argument. The McGovern study period started on July 1, 2008, instead of October

## 2. Changes in Antibiotics Did Not Confound the McGovern Study.

Dr. Borak next speculates that the change in antibiotic regimens from gentamicin to gentamicin plus teicoplanin during the McGovern study period confounded the findings of the study. Ex.A, Borak Rpt. at ¶¶ 32–35. Yet he cites no studies for the proposition that either antibiotic regimen is associated with increased DJI rates, and in fact, there are none.

Given the dearth of evidence supporting his opinion, Dr. Borak relies on two flawed premises. First, he asserts there is a “differential capacity of the antibiotics to act upon the bacteria that are most commonly associated with the infections.” Ex.B, Borak Dep. at 187:20-188:11. However, two published studies that address this very question find no meaningful difference in the effect of different antibiotic regimens and DJI rates. Ex.J, C. Hickson et al., *Prophylactic Antibiotics in Elective Hip and Knee Arthroplasty*, 4 BONE JOINT RES. at 186 (2015) (“[T]here is no clear benefit to using one particular [antibiotic] agent/regimen.”); Ex.K, A. Melling, *Effects of Preoperative Warming on the Incidence of Wound Infection After Clean Surgery*, 358 LANCET at 876 (2001) (“The value of prophylactic antibiotics in clean-contaminated and contaminated surgery is not contentious but the benefits of prophylactic antibiotics in reducing wound infection rates after clean surgery remain unclear.”). When faced with these articles on cross examination, Dr. Borak

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7, 2007, because Wansbeck Hospital had fully transitioned to full-time surveillance on July 1, 2008. Ex.D, Reed Dep. at 46:11–20. Given large data gaps prior to July 1, 2008, data collection before then would have been “very unreliable.” *Id.* at 64:2–7. Dr. Holford admits that he had no reason to doubt Dr. Reed’s testimony, undermining Dr. Borak’s reliance on Dr. Holford’s analysis. Ex.I, Holford Dep at 247:4-249:14. Because Dr. Holford’s time trend analysis does not meet the threshold for reliability under Rule 702, *see* Pls.’ Mem. to Exclude Holford at 17–19, Dr. Borak’s time trend testimony should be excluded, too.

agreed he had no reason to dispute the finding of the Hickson study that “there is no clear benefit to using one type of [antibiotic] agent” over another, thus unveiling that his opinion on confounding rests on nothing more than speculation . Ex.B, Borak Dep at 193:4-194:7.

Dr. Borak’s second theory is predicated on a comment he plucked out of an on-line newsletter article by Brister, which quoted Dr. Reed as stating: “Our infection rate doubled when we went to Gentamicin.” Ex.B, Borak Dep. at 187:20-188:11; Ex.L, Holford Dep. Ex. 24, A. Brister, *Infection Control in Orthopaedic Surgery*, CLIN SERVICES J (Nov. 9, 2011). Dr. Borak simply took this quote out of context, omitting the following statements: “There is no hard evidence to tell us what antibiotic we should be using. It is a really difficult problem and we need a trial.” Furthermore, Dr. Reed’s statement, as cited by Dr. Borak, does not apply to DJI rates but to wound infections in general. While the distinction between SSI and DJI is critical, Dr. Borak’s conflation of the terms led to his erroneous assumption that changing antibiotics confounded the findings of the McGovern study.

Dr. Holford fell prey to the same false assumption in his data manipulation of the McGovern data, upon which Dr. Borak relies for his opinions about confounding. Even then, Dr. Holford did not find that the change in antibiotic regimens from gentamicin to gentamicin plus teicoplanin significantly affected DJI rates between the BairHugger and conductive blankets. Ex.M, Holford Rpt. at 6. Professor Nachtsheim, both a coauthor of the McGovern study and statistics professor at the University of Minnesota, reached the same conclusion given the uncontested fact that DJI rates between the BairHugger and conductive warming groups remained significantly different when the same antibiotic (gentamicin plus teicoplanin) was used at Wansbeck. Ex.N, Nachtsheim Dep. at 332:20-

339:7. Professor Nachtsheim also determined that there was no scientific basis to conclude that the change in antibiotics confounded the McGovern study because there was no significant difference in DJI rates among patients who received either regimen. *Id.* at 339:8-17; *see also id.* at 349:22–23 (“I’m confident that those weren’t confounding factors.”).<sup>3</sup>

Although Dr. Holford did not review Professor Nachtsheim’s deposition testimony, he conceded at his deposition that because the change in antibiotic protocols did not meaningfully affect the change in DJI, he had no basis for controlling that variable as a confounder in his analysis. Ex.I, Holford Dep. at 322:5–7. This admission is fatal to Dr. Borak’s opinion given his reliance on Dr. Holford’s post-hoc remixed calculations regarding confounding. Ex.B, Borak Dep. at 186:7– 2. For these reasons, Dr. Borak’s testimony regarding antibiotic regimens is unreliable and irrelevant; it should be excluded.

### **3. Changes in Antithrombotics Did Not Confound the McGovern Study.**

Still following Dr. Holford’s lead, Dr. Borak further surmises that the change in thromboprophylactic regimens confounded the McGovern study. Ex.A, Borak Rpt. at ¶¶ 41–46. Dr. Borak’s opinion is rank speculation and lacks support for three reasons: (1) the Jensen study and multiple clinical trials did not find a difference in infection rates between these drugs; (2) relying on Dr. Holford’s erroneous data manipulations, Dr. Borak inappropriately concluded that the antithrombotic regimens were a “highly statistically

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<sup>3</sup> Scientifically, this conclusion makes sense. As Dr. Reed explained at his deposition, bacteria produce biofilm on joint prosthetics that protect them from antibiotics and other mechanisms the body might use to eliminate deep joint infections. Ex.D, Reed Dep. at 184:8–12. Dr. Borak agrees with this explanation. Ex.B, Borak Dep. at 186:13-187:2.

significant confounder” of the McGovern study; and (3) finally, controlling for non-confounding variables is misleading and contrary to established scientific methodology.

**i. The scientific literature contradicts Dr. Borak’s opinion.**

Yet again, Dr. Borak pulls a quote out of context in order to bolster his “scientific” opinion. In a 2011 on-line newsletter article by Andrew Brister, Dr. Borak makes much ado of Dr. Reed’s statement that “[w]e changed to Rivaroxaban from Tinzaparin and found that returns to theatres from wound complications more than doubled.” Ex.A, Borak Rpt. at ¶ 41. Dr. Borak makes the same mistake here as he does throughout his report: he improperly yet continually conflates wound complications with deep joint infections despite his awareness of their very distinct etiologies. Ex.B, Borak Dep. at 83:18-84:18.

What’s more, in the Brister article, Dr. Reed was referring to a study that he and Dr. Jensen had just completed. Ex.O, C. Jensen, *Return to theatre following total hip and knee replacement, before and after the introduction of rivaroxaban*, 93-B(1) J BONE & JOINT SURGERY, 91, 93 (2011). The Jensen study compared DJI rates for 489 patients who received tinzaparin and 559 patients who received Xarelto, the same thromboprophylaxis regimens used in the McGovern study. While the study found a significant difference in “wound complications” between patients receiving Xarelto versus tinzaparin—just as Dr. Reed said in the Brister article, it did not find significant differences in DJI between patients receiving Xarelto versus tinzaparin; rather, the study reported “similar” DJI rates. *Id.* at 93.

The Jensen study corroborates the subsequent findings of the Jameson and Reed study, which analyzed 13,000 patients who took Xarelto versus enoxaparin—a low molecular weight heparin similar to tinzaparin. Ex.P, S Jameson, *Wound Complications*

*Following Rivaroxaban Administration*, 94 J BONE JOINT SURG AM 1554-8 (2012). Like the Jensen study, the Jameson and Reed study found that Xarelto significantly increased “wound complications” compared to low molecular weight heparins, but it did not find a significant difference between these regimens in terms of DJI as the outcome. *See id.* at 1556, Table II (showing no significant difference for “return to surgery for infection”).

Moreover, four randomized controlled trials—also known as the RECORD trials—found no significant difference in infection rates between Xarelto and low molecular weight heparins similar to tinzaparin. Ex.Q, B. Eriksson, *Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Hip Arthroplasty*, 358(26) N. ENGL. J. MED. (2008); Ex.R, A. Kakkar, *Extended Duration Rivaroxaban versus Short-Term Enoxaparin for the Prevention of Venous Thromboembolism after Total Hip Arthroplasty*, 372 LANCET 31-39 (2008); Ex.S, M. Lassen, *Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Total Knee Arthroplasty*, 358(26) N. ENG. J. MED. (2008); Ex.T, A. Turpie, *Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Total Knee Arthroplasty (RECORD 4)*, 373 LANCET 1673-80 (2009). Drs. Borak and Holford ignore these contrary studies despite their coherence with the widespread consensus that antithrombotics do not affect DJI rates.

Courts have cautioned that an expert’s opinion is unreliable if it fails to acknowledge or account for relevant scientific literature that tends to refute the expert’s theory. *See Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 519 (S.D.W. Va. 2014) (collecting cases). Dr. Borak professed to search the relevant literature in developing his opinions for this litigation. Ex.B, Borak Dep. at 27:8-28:10. Inexplicably, however, he omitted a series of studies—ranging from the Jensen and Jameson papers all the way to the four well-known

RECORD trials—as sources of information to determine whether antithrombotic regimens were associated with increased DJI rates. His failure to consider the great weight of contrary scientific evidence vitiates his opinion that antithrombotic drugs are confounders.

**ii. Dr. Borak erroneously relied on a remix of the McGovern study by applying infection criteria from an entirely different study.**

Unable to cite scientific studies favoring his opinion, Dr. Borak resorts to arguing that “significant differences” between the Jensen and McGovern studies invalidate Dr. Samet’s conclusion that antithrombotic medications are not confounders. Ex.A, Borak Rpt. at ¶43. Dr. Borak assumes that because the McGovern study and the Jensen study both occurred at the Wansbeck Hospital, the McGovern study must be wrong since the authors reported fewer BairHugger surgeries than Jensen et al. *Id.* As stated in both peer-reviewed publications, however, each study used different intake criteria—a fact that Dr. Borak concedes in his report. *Id.* at ¶ 44. The McGovern study used a 60-day cut-off for infections and excluded trauma patients, while Jensen et al. used a 30-day cutoff and included trauma patients. *Id.* at ¶ 44. It is inappropriate to remix studies with different inclusion criteria.

Despite this methodological error, Dr. Borak relies on Dr. Holford’s statistical manipulation of the McGovern data, which cherry-picked information from the Jensen study to make it appear that the higher DJI rate in patients taking Xarelto compared to tinzaparin was a “highly statistically significant confounder” of the McGovern study. Ex.A, Borak Rpt. at ¶ 44. However, Dr. Holford admits that his “remixed” analysis to control for antithrombotic and antibiotic variables was not part of the design of either study he cites. He also admits that he reduced the patient population by half, underpowering his analysis,

and that his unpublished calculations create twice as much variance (and thus unreliability) as the original McGovern data. *See* Pls.’ Mem. to Exclude Holford at 29. *Accord* Ex.U, Albrecht Dep. at 217:23-218:4; Ex.N, Nachtsheim Dep. at 340:5–11. Accordingly, Dr. Borak’s testimony cannot stand because it is based on Dr. Holford’s unreliable analysis.

**iii. Controlling for Nonconfounding Variables Violates Generally Accepted Methodology.**

Statistical treatises caution against treating a variable as a confounding factor if there is good evidence from prior studies that the variable is not associated with the outcome at issue. Ex.V, N. Breslow and N. Day, *Statistical Methods in Cancer Research*, [103-107] (Int’l Agency for Research on Cancer, Lyon FR – 198). Outside the courtroom, Dr. Holford makes this very point, arguing that “one can lose precision by unnecessarily adjusting for a covariate” when the variable is known to be associated with exposure but not in itself related to disease. Ex.W, T. Holford, *Confounding in Epidemiologic Studies*, 45 *BIOMETRICS* at 1320 (1989). Yet that is precisely what Dr. Borak and Dr. Holford do here.

At his deposition, Dr. Holford admitted that his calculation for determining whether the change in thromboprophylaxis confounded the McGovern study was “not a good estimate.” Ex.I, Holford Dep. at 219:1–23. He also admitted that his calculations were less reliable than the McGovern study—the very publication he attacks. *Id.* at 221:22-222:3. By inserting a false confounder, Dr. Holford deliberately created imprecision in the data he manipulated. Because Dr. Borak adopts Dr. Holford’s unreliable calculations on confounding and never questioned or even attempted to correct them, his opinion testimony should be excluded for the same reasons. *See* Pls.’ Mem. to Exclude Holford at 26, 29.

#### 4. The Use of MSSA Screening Did Not Confound the McGovern Study.

Dr. Borak next speculates that the adoption of a nasal screening procedure for methicillin-sensitive staphylococcus aureus (“MSSA”) during the McGovern study period confounded the study’s results. Ex.A, Borak Rpt. at ¶¶ 36–38. He relies on three studies, but two of them do not support his opinion because they do not differentiate between DJI and other types of infection. Ex.X, A. Chen et al., *Staphylococcus aureus screening and decolonization in orthopaedic surgery and reduction of surgical site infection*, 471 CLIN ORTHOP RELAT RES 2383-2399 (2013); Ex.Y, M. van Rijen, *Mupirocin ointment for preventing Staphylococcus aureus infections in nasal carriers (Review)*, COCHRANE DATABASE OF SYSTEMATIC REVIEWS (Wiley & Sons 2011). The third study does not help him for another obvious reason—it does not analyze the impact of MSSA screening but finds no clear benefit to using one antibiotic over another. Ex.J, D. Hickson, *Prophylactic antibiotics in elective hip and knee arthroplasty*, 4(11) Arthroscopy 181 (2015).

At his deposition, Dr. Borak admitted that his analysis of MSSA infection rates improperly grouped together all types of infection, regardless of whether they were DJI. Ex.B, Borak Dep. at 203:4-204:19. He also conceded that it would not be a fair comparison to apply the SSI studies he cites throughout his report, which include all types of wound infections, to DJI—the outcome considered in the McGovern study. *Id.* at 201:4-202:25.

Instead, Dr. Borak resorts to a quote from Dr. Reed, which he presumes linked MSSA screenings to reductions in DJI at Wansbeck Hospital. *Id.* at 202:4–14. But that article specifically noted that the reduction in MSSA rates occurred after use of other infection prevention methods and that it was the “switch to alternative conductive fabric

warming [that] led to the significant decrease in deep injection rates.” Ex.Z, R. Refaie et al., *Prevention of Periprosthetic Joint Infection*, 3(3) J TRAUMA & ORTHOPAEDICS 50-52, at 51 (Sept. 2015) Dr. Borak not only ignores this unequivocal statement in the very article he cites, but he disregards Dr. Reed’s additional testimony that there is no evidence that MSSA screening reduces DJIs. Ex.D, Reed Dep. at 113:23-115:10. Perhaps that explains why Dr. Borak could not remember whether he had cited any scientific literature supporting an association between MSSA and DJI. *See* Ex.B, Borak Dep. at 231:14–25.

Absent any evidence from the published literature to support his conclusion, Dr. Borak’s assumption that MSSA screening confounded the McGovern study amounts to sheer speculation. These assumptions should be excluded. *See Sorensen*, 31 F.3d at 649.

### **5. Changes in Skin Preparation Did Not Confound the McGovern Study.**

Dr. Borak further postulates that changes in surgical site skin cleaning protocols confounded the McGovern study, based again on a quote from Dr. Reed in Brister’s on-line newsletter article and a handful of papers that do not differentiate between DJI and other types of infections. Ex.A, Borak Rpt. at ¶¶ 39–40. Dr. Borak admits he cannot point to a single study to support his opinion that skin preparation is associated with DJI rates:

Q. – of a pub --- of a published study that suggests a material difference between the two skin-preparation protocols and a risk of a deep joint infection?

A. I don’t know that I can point to one now, but this again is something to which I will defer to Dr. Wenzel.

\* \* \*

Q. but my point is is you – you said at the beginning of this module that we started that you do believe it’s a confounder, but you’ll agree with me that you don’t have any evidence that the skin – change in skin preparation during the McGovern period was –

A. I do not have a direct comparison –

Q. Right.

A. – to offer you today.

Q. Right. But you're still comfortable saying there's an association.

A. I think that there might be.

Ex.B, Borak Dep at 177:14-20, 178:3-15.

Dr. Borak's skin preparation confounder theory thus unquestionably rests not on a reliable methodology but rather on pure speculation. This testimony should be excluded.

#### **6. The Hawthorne Effect Did Not Confound the McGovern Study.**

The most bizarre opinion Dr. Borak espouses is that a psychological phenomenon dubbed the "Hawthorne Effect" confounded the McGovern study. Ex.A, Borak Rpt. at ¶ 47. This effect occurs when participants in an experiment modify their behavior when they know they are being observed. *Id.* Dr. Borak posits that the Hawthorne Effect is a confounder (over and above the other alleged confounders) because Wansbeck Hospital staff knew they were being watched and were more careful in following SSI protocols, which yielded a better outcome for patients who received conductive warming. *Id.* at ¶ 48.

Dr. Borak's theory is classic conjecture. He admits he has "no idea" if any of the hospital staff knew they were participating in the McGovern study because the data was gathered *after* the time period in which the patients were hospitalized. Ex.B, Borak Dep. at 154:1–10. The court should exclude this testimony because it is unreliable and irrelevant.

#### **C. Dr. Borak Should Not Be Allowed to Express an Opinion on General Causation Because He Failed to Apply Proper Methods**

Dr. Borak's testimony on general causation rests entirely on the assumption that the McGovern study is *per se* invalid and therefore provides no evidence of an epidemiological

association between the BairHugger and DJI. Unlike Dr. Samet, Dr. Borak did not consider the Bradford Hill criteria or conduct a similar analysis to determine whether the association reported by the McGovern study is causal. Instead, Dr. Borak admits the “sufficient component cause model” used by Dr. Samet is a reliable methodology but nevertheless attacks Dr. Samet for undertaking this analysis, ultimately making the circular argument that the McGovern study does not establish an association. Ex.B, Borak Dep. at 66:9–22.

Dr. Borak admits he did not investigate, read, or otherwise rely on other non-epidemiologic evidence to inform his opinions about causation in this case. Indeed, he did not review any published studies describing the mechanism for how BairHugger can cause DJI, though he admits that internal contamination of the device could increase the risk of infection. *Id.* at 109:11-17. Dr. Borak merely states that “[i]n the absence of valid evidence of a causal association between BH and [*sic*] SSI, it can only be said that the mechanistic studies are coherent with a hypothetical increase in [*sic*] SSI.” Ex.A, Borak Rpt. at ¶ 71. He even admits he is not qualified to give expert opinions on the mechanisms of infection and the peer-review scientific studies concerning them. Ex.B, Borak Dep. at 30:12–21.

In sum, Dr. Borak has limited the scope of his testimony to the McGovern study—and the McGovern study alone. Dr. Borak should not be allowed to express opinions about the Bradford Hill criteria or similar methods of analyzing causation because those methods apparently do not inform his opinion. Nor should Dr. Borak be permitted to testify about non-epidemiological studies on mechanism of DJI—a topic he professes to know nothing about. Such testimony lacks a reliable foundation, is irrelevant, and will not assist the jury.

## V. CONCLUSION

For the reasons stated above, the Court should exclude the testimony of Dr. Borak.

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